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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,365	01/31/2001	Suman Khowala	8920-000005	3998

7590 07/10/2003

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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07/10/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/773,365

Applicant(s)

KHOWALA ET AL.

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 3 and 6-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 6-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The amendment filed 6/11/03 is acknowledged. Claims 3, and 6-12 are being considered on the merits.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3 and 6-12 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sengupta *et al.* (1990) taken with Kubicek *et al.* for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to a process of producing an enzyme preparation containing "high" cellobiase activity in the presence of any glycosylation inhibitor, including tunicamycin or 2-deoxy-D-glucose with *Termitomyces clypeatus*.

Sengupta *et al.* (1990) disclose a process of producing an enzyme preparation containing cellobiase under conventional conditions with *Termitomyces clypeatus* (See, e.g., page 310).

The reference differs from the invention as claimed in the presence of a glycosylation inhibitor in the process. However, Kubicek *et al.* disclose the production of an enzyme preparation of *Trichoderma reesei* containing cellobiase in the presence of the glycosylation inhibitors tunicamycin or 2-deoxy-D-glucose in a concentration of about 50 µg/ml in similar process of producing an enzyme preparation (See, e.g., pages 700 and 701). In view of the similarity of the metabolic pathways involved in the biosynthesis of cellulolytic enzymes, including enzyme preparations containing high cellobiase, in fungi one of ordinary skill in the art would have had a reasonable expectation of success in obtaining a similar improvement in the stability of the excreted cellobiase produced, at least when using 50 µg/ml tunicamycin or 2-deoxy-D-glucose in the process (See, e.g., Kubicek *et al.* page 398, col. 2). In addition, Sengupta *et al.* recognize that the cellobiase enzyme in *T. clypeatus* is excreted and is regulated by catabolic repression and is sensitive to glucose inhibition (See, e.g., pages 310 and 314, last paragraph, respectively).

It is noted that the amounts provided in the reference correspond more closely to the amounts provided in the instant specification at page 9 of 0.05-2 mg/ml which show favorable results for a specific strain of *T. clypeatus*, rather than 0.05-5% as claimed. It is noted, for

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example, that the cellobiase activity using 5 mg/ml 2-deoxy-D-glucose is a low 0.081 units/ml compared to the control of 1.044.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Sengupta *et al.* for producing an enzyme preparation containing high cellobiase with *Termitomyces clypeatus* by adding a glycosylation inhibitors tunicamycin or 2-deoxy-D-glucose as taught by Kubicek *et al.* for the expected benefit of increasing the stability of the secreted cellobiase useful for the degradation of cellulose-containing agrowastes, for example.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants argue that similarity in metabolic pathways is unfounded as a basis of rejection because in *T. clypeatus* extracellular secretion of cellobiase and not production is regulated by catabolic repression. However, the arguments by counsel in this regard have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence. In addition, arguments directed to 50 microgram/ml of 2-deoxyglucose are not clearly commensurate in scope with the claimed invention.

It is noted that the present invention recognizes that 2-deoxyglucose acts *in vivo* as a glycosylation inhibitor. However, the independent claim is directed to the use of any glycosylation inhibitor. (Supplemental response, page 2).

In response to applicants' argument that Kubicek does not disclose the production of cellobiase in the presence of a glycosylation inhibitor, it must be noted that the as filed specification at page 3, paragraph 3 it is admitted that Kubicek discloses that the "production and secretion of cellobiase in *Trichoderma reesei*" was studied in presence of glycosylation inhibitors. In addition, the claimed invention is not drawn to the production of cellobiase, but rather to the production of a mixture of enzymes, i.e., an enzyme preparation containing "high" cellobiase activity. No clear definition of "high" activity is found in the as-filed specification. for the amount of cellobiase activity required to meet this limitation.

Therefore the rejection is deemed proper and it is adhered to.

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No claim is allowed.

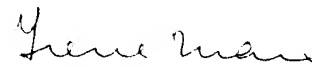
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



Irene Marx
Primary Examiner
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